



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/529,543 04/14/00 SCHWARZ

E MERCK-2084

HM22/0912  
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EXAMINER

TRAN, S

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

09/12/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/529,543

Applicant(s)  
Schwarz et al.

Examiner  
Susan Tran

Group Art Unit  
1615



- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-18 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☒ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

Receipt is acknowledged of applicants' Preliminary Amendment A filed 04/14/00, and Information Disclosure Statement filed 08/10/00.

#### ***Claim Objections***

1. Claim 10 is objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits. It is suggested to amend to "according to any one of claim 1 to 9".

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-8, and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite in the use of the phrase "characterized in that xylitol and mannitol, xylitol and lactitol or xylitol, mannitol and lactitol are employed as polyols", the language is confusing. Correction is requested.

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Claims 6 and 7 are indefinite in the use of the phrase “range between 90:10 to 98:2, in particular between 90:10 to 95:5”, the language is considered to be a range within a range. It is not clear if the range is limiting or just exemplary. Correction is requested by the elimination of one of the range.

Claim 8 is indefinite in the use of the phrase “range between 90:1:9 or 90:9:1 and 98:1:1”, the language is considered to be a range within a range. It is not clear if the range is limiting or just exemplary. Correction is requested by the elimination of one of the range.

Claims 16-18 are indefinite in the use of the phrase “selected from the group”. If Markush language is intended, the appropriate phrasing is “selected from the group consisting of”.

### *Claim Rejections - 35 USC § 101*

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Use claims are not considered to be one of the permitted classes of invention. Applicant should recite a method or process that includes at least one step.

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***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9, 12, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Virtanen et al. USPN 5,536,526 ('526).

Virtanen teaches a composition comprising about 94% to 98% by weight of xylitol, less than about 1% by weight of water, and about 1% to about 5% by weight of acceptable polyol other than xylitol, such as mannitol, lactitol, sorbitol, maltitol and isomalt (column 5, lines 39-53). The composition can prepared by the method of granulating, drying in a fluidized bed and then directly compress into tablet (column 7, lines 21 through column 8, lines 1-21).

5. Claims 1-5, 12-16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Olinger et al. USPN 5,204,115 ('115).

Olinger teaches a composition comprising about 95% to 99% xylitol, sweetener, i.e. saccharin, acesulfame K, cyclamate, or sucralose, and about 0.1% to about 5% other polyol, such as mannitol, lactitol, sorbitol, maltitol and isomalt (column 6, lines 53 through column 7, lines 16-22). The composition further comprising water soluble additions such as polydextrose containing citric acid (column 7, lines 51-55).

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Regarding to claims 3 and 4, the cited reference is silent as to the teaching of spray drying at a temperature of from 120°C to 300°C, however, it is the product that's being determine for patentability. The patentability of a product does not depend on its method of production.

*Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen et al. ('526), in view of Schwarz et al. USPN 5,958,471, and Mizumoto et al. USPN 5,576,014.

Virtanen is relied upon for the reason stated above. The cited reference differs from applicants claimed invention by not specifically teaching the temperature of drying solution of polyols.

Schwarz teaches a composition comprising xylitol and other polyol, and additives such as citric acid sweetener, citric acid, or vitamins (column 2, lines 39 through column 3, lines 1-31). The composition is directly suitable for the production of compacted articles, and can be obtained by the process disclosed in column 2, lines 32-63).

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The cited references are silent as to the teaching of pharmaceutical additives, such as antacid or analgesic agents.

Mizumoto teaches a composition comprising xylitol, lactose, mannitol, glucose, sucrose or sorbitol (column 6, lines 37-46), analgesics and antacid agents are listed in column 7, lines 62 through column 9, lines 1-43). The composition is then compressed into tablet (column 13, lines 16-24).

The examiner notes that Schwarz teaches the concentration of xylitol is less than other polyols concentration, however, it is the examiner's position that no criticality is seen in the use of the particular amount since the prior art obtains the same results desired by applicant, i.e. a direct compressed tablet. The amount has not been shown to provide any unusual and/or unexpected results over the applied prior art. Thus, it would have been prima facie obvious for one of the ordinary skill in this art to prepare the Virtanene's composition with Mizumoto's pharmaceutical ingredients using the method in view of the teaching of Schwarz to obtain a direct compressed tablet contains more than 90% of xylitol.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600